

REMARKS

The present invention relates to a stent and to a method of treatment of a patient needing a stent or needing removal of a stent.

In the Office Action dated September 2, 2009, claims 1, 3, 4 and 16-45 were rejected. Particularly, at pages 2-5, claims 1, 3, 4, 16, 17, 31-34, 37, 39, and 41-45 were rejected under 35 U.S.C. § 103(a) based on Phan et al (US Patent 5,603,722) and Langer et al (US 6,388,043), with the Examiner relying on Phan et al as the primary reference, and relying on Langer et al as disclosing shaped memory polymers which have two stimulus-triggered memory shapes. Claims 28, 29, 38, and 40 were similarly rejected, with the Examiner referring to Phan et al as disclosing that the SMP can comprise a caprolactone unit, etc., and the Examiner similarly relied on specific portions on the Phan et al reference for disclosing the features recited in claims 30, 35, and 36 (at page 4 of the Office Action).

In the present Amendment, Applicant has amended method claims 32 and 35 to independent form, and has cancelled method claims 33, 34 and 36 in view thereof. Particularly, claims 32 and 35 have been amended to place the claims directed to a method of treatment of a patient needing a stent, and a method of treatment of a patient needing removal of a stent, into independent form with detailed recitations as to the steps undertaken, including thermal change steps. Referring to the corresponding U.S. Patent Application Publication US 2007/0129784 A1 for the Examiner's convenience, support for amended independent method claims 32 and 35 is provided, e.g., based on paragraphs [0041-0045], [0054-0058], and [0067-0070] (for claim 32) and paragraphs [0047-0052], [0060-0064], and [0072-0076] (for claim 35).

Also, claims 3, 4, and 17-30 have been amended to depend on method claim 32; claims 38-40 have been amended to depend on method claim 35; and claims 16, 31, 37, and 41-45 have also been cancelled.

Applicant discusses independent method claims 32 and 35 in further detail below.

The present invention according to claim 32 above relates to a method of implanting the stent which is either exclusively made of a shape memory polymer (SMP) or of a SMP covering a non-shape memory material . The method, in relevant parts, comprises the insertion of the stent disposed on a balloon catheter, wherein the stent is present in its permanent form, i.e. it has not been programmed before by a thermo-mechanical procedure. The programming procedure is conducted *in vivo* at the desired position in the body, for instance in a blood vessel. For programming the temporary form, the stent is heated above the transition temperature of the SMP and expanded by means of the balloon until the stent has its desired diameter to support the vessel. Then the temporary form is fixed either by cooling the SMS below T_{trans} or by irradiating with light of a suitable wavelength. Then the catheter is removed.

Claim 35 relates to a corresponding method of removing the stent from the implantation site involving the step of heating the stent above the T_{trans} or irradiating with light of a suitable wavelength. In this way the shape memory effect is activated, meaning that the stent spontaneously recovers its permanent compressed shape.

According to the present invention, the stent is implanted in its permanent compressed form, brought into a temporary expanded form *in vivo*, and, after recovery of the permanent form by the shape memory effect, removed in its permanent compressed form. Thus, the present invention enables to easily insert the stent in a compressed shape, wherein the expanded state is programmed only *in vivo* within the body by exerting an expanding force by means of the balloon and a suitable stimulus (heat or light). Moreover, by simply activating the shape memory effect by again exerting a suitable stimulus, the stent recovers its compressed permanent form and can thus be easily removed.

Prior art

Phan et al (US 5,603,722) disclose a stent essentially consisting of a non-metallic SMP. The stent is implanted in its “closed, high-curvature condition” as shown in Figures 1B, 2B or 3B and is then caused, by the supply of a stimulus such as heat, to undergo a shape transition to an “expanded, low-curvature condition” as shown, e.g., in Figures 1C, 2C or 3C, respectively (see also col. 5, lines 40-44).

However, in contrast to present claim 32, the “closed, high-curvature condition” corresponds to a temporary shape which has been programmed before insertion into the body using a process as described in column 5, lines 45-55. In order to expand the stent, a stimulus is exerted, causing the transition from the temporary shape to the “original shape” or “memory condition” corresponding to the permanent form (col. 5, lines 40-44).

Thus, as to claim 32, Phan et al fails to disclose to insert the stent existing in its permanent compressed shape and fails to disclose to program the temporary expanded shape at the implantation site. As to claim 35, Phan et al fails to disclose to recover the permanent compressed shape for removing the stent. Thus, it is seen that Phan et al actually teaches the opposite approach *vis-a-vis* the present invention. The approach of Phan does not enable an easy removal of the stent as it exists at the implantation site in its permanent expanded shape.

Langer et al (US 6,388,043 B1) generally relates to shape memory polymeric materials and discloses a large number of applications of the SMP materials, including therapeutic, prophylactic and diagnostic applications, articles and devices for biomedical applications, such as implants, and non-medical applications, column 15, line 49 to column 17, line 35. In this generalized disclosure, stents are also mentioned. However, Langer et al fail to disclose any method of inserting or removing a stent.

Since none of the cited references disclose the programming of the temporary form *in vivo* and to use the shape memory effect for removing the stent, the present invention according to claims 32 and 35 cannot considered to be obvious over the cited prior art.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned attorney at the local Washington, D.C. telephone number listed below.

AMENDMENT UNDER 37 C.F.R. § 1.111
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Respectfully submitted,

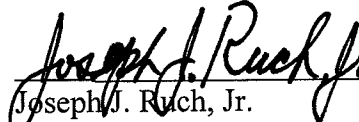
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